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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/633,657 | 08/05/2003 | Chieh-Fu Chen | 3358-0145P | 5467 |
| 2292 | 7590 | 02/03/2006 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH | | | COE, SUSAN D | |
| PO BOX 747 | | | ART UNIT | PAPER NUMBER |
| FALLS CHURCH, VA 22040-0747 | | | 1655 | |

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/633,657 | Applicant(s) CHEN ET AL. | |
| | Examiner Susan D. Coe | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 and 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-4 are currently pending.

Election/Restrictions

2. Applicant's election of Group I, claims 1, 3, and 4 in the reply filed on December 14, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 14, 2005.

4. Claims 1, 3, and 4 are examined on the merits.

Claim Objections

5. Claims 1, 3, and 4 are objected to because of the following informalities: Independent claims 1, 3, 4 should begin with "A specially" rather than "The specially." In addition, claims 3 and 4 contain more than one sentence. Patent claims should be only one sentence long. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1655

Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

7. Claims 1, 3, and 4 are indefinite because it is unclear what is meant by “specially processed” and if applicant intends for this phrase to convey limitations on the claims.

8. The use of “such as” in claims 3 and 4 is indefinite because it is unclear if the alkaloids listed are required elements of the claim. In addition, it is unclear what amounts of the compounds must be present in order to meet the limitation of “main” components. In addition, the use of “could be” is considered narrative language which is inconsistent with currently US practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou et al. (Journal of Chinese Medicine (March 2002), vol. 13, no. 1, pp. 39-48).

Art Unit: 1655

Chou teaches an extract from *Stephania tetrandra* roots that contain tetrandrine, fangchinoline, cyclanoline, and oblongine. The reference teaches that extract from *S. tetrandra* can be used as pharmaceutical compositions to modulate cardiovascular disorders and to treat inflammation (see page 40).

10. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,218,541.

US '541 teaches an extract from *S. tetrandra* roots. The reference specifically teaches that the extract contains tetrandrine, fangchinoline and cyclanoline (see figure 1). The reference does not specifically teach that oblongine is present in the extract. However, as the extraction procedure used by US '541 is extremely similar to the extraction used by applicant to obtain the solution of the four alkaloids. Both the reference and the current specification teach extracting the roots of the plant using ethanol followed by concentration of this extract. Next, the concentrated extract is mixed with HCl. The acidic solution is then contacted with NH_4OH to bring the pH to 9. The solution is then contacted by chloroform. Both the reference and the specification teach that tetrandrine and fangchinoline are in the chloroform layer. The reference teaches that the alkaline solution contains cyclanoline. The reference does not teach that this solution has oblongine. However, since the extraction is the same as described by applicant, oblongine would have to be present in this layer (see figure 1 of US '541 and page 21, second paragraph of the current specification).

In addition, applicant's specification teaches that these four alkaloids are natural components of the *S. tetrandra* roots. Thus, these alkaloids would be an inherent component in any *S. tetrandra* root.

Art Unit: 1655

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



1-31-06

Susan D. Coe
Primary Examiner
Art Unit 1655